

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO.,  
LTD.,

Plaintiff,

v.

APOTEX CORP., APOTEX INC. and  
HETERO LABS LTD.,

Defendants.

HONORABLE JEROME B. SIMANDLE

Civil Action No.  
14-8074 (JBS/KMW)

**MEMORANDUM OPINION**

**SIMANDLE, Chief Judge:**

This patent infringement action, one of twenty-six related actions under the Hatch-Waxman Act, 35 U.S.C. §§ 271, 281, generally concerns Plaintiff Otsuka Pharmaceutical Co, Ltd.'s (hereinafter, "Otsuka") position that Apotex Corp.'s and Apotex Inc.'s (collectively, "Apotex") proposed generic aripiprazole product infringes one or more claims of four of the various patents covering Otsuka's Abilify® aripiprazole product, U.S. Patent Nos. 8,017,615 ("the '615 patent"), 8,580,796 ("the '796 patent"), 8,642,760 ("the '760 patent"), and 8,759,350 ("the '350 patent" and collectively, the "Patents-in-Suit").

Otsuka now moves to dismiss Apotex's Ninth and Tenth Counterclaims for "Unlawful Monopolization" and "Patent Misuse" (hereinafter, the "Counterclaims") pursuant to Federal Rule of Civil Procedure 12(b)(6) or, in the alternative, to bifurcate



and stay discovery on Apotex's Counterclaims pending resolution of the primary patent infringement issues pursuant to Federal Rule of Civil Procedure 42(b). [Docket Item 298.] The Court recently addressed the viability of substantively identical counterclaims in Otsuka Pharm. Co., Ltd. v. Apotex Corp., 143 F. Supp. 3d 188 (D.N.J. Aug. 11, 2015) ("Apotex I"), and reaches substantially the same result in connection with the pending motion. For the reasons that follow, Otsuka's motion will be granted in part and denied in part. The Court finds as follows:

1. For the purposes of the pending motion, the Court need not retrace the lengthy factual and procedural predicate for this action. Rather, it suffices to note that, in its amended Counterclaims for Unlawful Monopolization and Patent Misuse, Apotex alleges that Otsuka has engaged in a pattern of anticompetitive behavior that has caused a wide impact on the entire aripiprazole market.

2. Notably, in Apotex I, this Court denied Otsuka's motion to dismiss two of Apotex's counterclaims, but granted Otsuka's request to bifurcate and stay Apotex's antitrust and patent misuse Counterclaims. See 143 F. Supp. 3d at 197-98. The Court found that Apotex's allegations, accepted as true, sufficiently stated an antitrust injury, set forth plausible facts sufficient to overcome Otsuka's presumptive antitrust



immunity under the Noerr-Pennington doctrine, and sufficiently stated a claim of patent misuse. Id. at 194, 196-97.

3. Because the briefing in Apotex I preceded the July 2015 approval of Apotex's ANDA and the commercial launch of its generic aripiprazole tablet products, Otsuka has renewed its motion to dismiss Apotex's two Counterclaims. (Otsuka's Br. at 2-3.)

4. Specifically, Apotex's "Unlawful Monopolization" Counterclaim alleges, in particular, that Otsuka "has the power to control prices and/or exclude competition in, or prevent entry into" the aripiprazole market, and claims that Otsuka has "exercised monopoly power in the relevant market." (See Countercl. at ¶¶ 90-91.) Indeed, Apotex claims that Otsuka has "engaged" in an "overall predatory scheme to monopolize" the aripiprazole market through its institution of "objectively baseless and sham judicial proceedings designed to continue its monopoly of aripiprazole tablets" and to prevent Apotex, among other generic companies, from competing in the aripiprazole market. (Id. at ¶¶ 98-101.) Apotex therefore alleges that this infringement litigation amounts to "sham" and "bad faith" litigation, in violation of the Sherman and Clayton Acts, 15 U.S.C. §§ 2, 15, and 26. (Id. at ¶¶ 82-123.)

5. Apotex's "Patent Misuse" Counterclaim largely reiterates the allegations of its "Unlawful Monopolization"



Counterclaim, and specifically alleges that Otsuka "intentionally engaged in the exclusionary conduct" in an effect to achieve and maintain monopoly power in the market of aripiprazole tablets, and that Otsuka's "anticompetitive activities are a direct, proximate, and reasonably foreseeable cause" of Apotex's delayed entry into the market. (Id. at ¶¶ 115, 117.) Apotex further alleges that Otsuka's infringement claims against Apotex are "objectively and subjectively baseless" and that Otsuka has acted "solely to exclude potential competition from an alternative source" in the aripiprazole market (Id. at ¶¶ 111, 120.)

6. In moving to dismiss Apotex's Ninth and Tenth Counterclaims, Otsuka argues, as it did in connection with substantially similar counterclaims in Apotex I, that Apotex's antitrust and patent misuse Counterclaims must be dismissed, because (1) Apotex has not alleged the "antitrust" or "anticompetitive" injury" required for antitrust standing; (2) Apotex cannot "plausibly support a nexus between its delay in receiving approval of its ANDA and any actions by Otsuka;" and (3) Apotex's patent misuse counterclaim fails as a matter of law to state a cognizable claim for patent misuse. (See Otsuka's Br. at 5, 7-8.) In the alternative, Otsuka requests that the Court bifurcate for trial the patent issues raised in this litigation



from the antitrust and/or patent misuse issues. (Otsuka's Br. At 9).

7. Under Federal Rule of Civil Procedure 12(b)(6), the court must generally accept as true the factual allegations of the defendant's counterclaims, and construe all "reasonable inferences" in the light most favorable to the defendant. Revell v. Port Auth. Of N.Y., N.J., 598 F.3d 128, 134 (3d Cir. 2010); see also Fleisher v. Standard Ins. Co., 679 F.3d 116, 120 (3d Cir. 2012) (same). However, "[a] pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action" fails to suffice. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). Rather, the "well-pled factual allegations" must be sufficient to demonstrate a plausible "entitlement to relief." Iqbal, 556 U.S. at 678 (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)); see also Umland v. PLANCO Fin. Serv., Inc., 542 F.3d 59, 64 (3d Cir. 2008).

8. As stated above, Otsuka moves to dismiss Apotex's "Unlawful Monopolization" Counterclaim for lack of standing, and moves to dismiss Apotex's patent misuse Counterclaim for failure to state a plausible claim for relief. For substantially the same reasons stated in Apotex I, the Court will deny Otsuka's motion to the extent it seeks the dismissal of Apotex's



Counterclaims. The Court will briefly address each issue in turn.

9. A party suing under federal antitrust laws, as here, must meet the prudential requirement of "antitrust standing." Ethypharm S.A. France, 707 F.3d 223, 232 (3d Cir. 2013). In Ethypharm S.A. France, the Court of Appeals for the Third Circuit outlined a five-factor test, with the second, "antitrust injury," constituting the essential precondition for antitrust standing. Id. (citation omitted.) In other words, in the absence of a plausible allegation of antitrust injury, the only factor presently challenged by Otsuka, the Court need not reach the remaining factors.

10. As stated by this Court in Otsuka Pharm. Co., Ltd. v. Torrent Pharm. Ltd., Inc., 118 F. Supp. 3d 646 (D.N.J. 2015) ("Torrent I"),

In order to plead an antitrust injury, the party must allege facts showing (1) that it suffered an injury of the type the antitrust laws seek to prevent, e.g., anticompetitive behavior, and (2) that the injury resulted from the adversary's unlawful or anti-competitive acts. See In re Niaspan Antitrust Litig., 42 F. Supp. 3d 735, 753 (E.D. Pa. 2014) (quoting In re K-Dur Antitrust Litig., 338 F. Supp. 2d 517, 534 (D.N.J. 2004)). The federal antitrust laws, however, foster "the protection of competition not competitors.'" Race Tires Am., Inc. v. Hoosier Racing Tire Corp., 614 F.3d 57, 76-77 (3d Cir. 2010); see also Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 488 (1977) (citation omitted) (noting that Congress enacted the antitrust laws "for 'the protection of competition, not competitors'"). As a result, the pleaded facts must show "that 'the



challenged action has had an actual adverse effect on competition as a whole in the relevant market," rather than just an adverse effect on the particular competitor. Irish v. Ferguson, 970 F. Supp. 2d 317, 365 (M.D. Pa. 2013) (citations omitted); see also Eichorn v. AT&T Corp., 248 F.3d 131, 140 (3d Cir. 2001) (noting that an antitrust injury does not lie unless the allegedly anticompetitive conduct "has a wider impact on the [overall] competitive market").

Torrent I, 118 F. Supp. 3d 646, 652 (footnote omitted).

11. The Court will next address whether Apotex's allegations prove otherwise sufficiently plausible on the issue of antitrust injury.

12. The "hallmark" for evaluating the plausibility of an allegation of antitrust injury is whether "the actions alleged to be anticompetitive when viewed 'as a whole' bear consequence for the overall market, rather than only for an individual competitor." Torrent I, 118 F. Supp. 3d at 653 (quoting TransWeb, LLC v. 3M Innovative Props. Co., No. 10-4413, 2011 WL 2181189, at \*18 (D.N.J. June 1, 2011)). Here, Apotex's antitrust Counterclaim alleges, in essence, that Otsuka has initiated meritless infringement actions and subsequently pursued preliminary injunctions against ANDA filers, in order "to prevent any and all competitors from competing in the marketplace" and to maintain its exclusive monopoly over the aripiprazole market. (Countercl. at ¶ 99.) Apotex further alleges that Otsuka's "exclusionary, anticompetitive and unlawful activities" have excluded "alternative source[s]" of



aripiprazole tablets and have, in particular, forestalled and frustrated Apotex's ability to compete in the aripiprazole market. (Id. at ¶¶ 120-123.)

13. For largely the reasons stated in Apotex I, Apotex's Counterclaim plausibly alleges the elements of an antitrust injury, namely, "an injury of the type protected by the antitrust laws, and that the injury derived, at least in part, from anti-competitive acts." Apotex I, 143 F. Supp. 3d at 194. Indeed, the pursuit of litigation that forestalls entry into the generic market and effectively extends a long-standing monopoly, as alleged here, constitutes precisely the type of "anti-competitive behavior" that the antitrust laws seek to redress. See id. Apotex alleges numerous instances of Otsuka injuring the entire aripiprazole market (and not just Apotex itself), including (1) Otsuka's March 2015 motion for a TRO and preliminary injunction "against any generic company that had the potential to launch a competitive product" in the aripiprazole market (Countercl. at ¶ 93) (emphasis added); (2) Otsuka's April 2015 suit against the FDA in the United States District Court for the District of Maryland seeking to "preclude approval of any generic versions" of Otsuka's product" (id. at ¶ 95) (emphasis added); and (3) that in filing these various suits, Otsuka "sought to prevent any and all competitors from competing in the marketplace." (Id. at 99.)



14. Further, while this Court recently addressed similar allegations in Otsuka Pharm. Co., Ltd. v. Torrent Pharm. Limited, Inc., No. 14-4671, 2016 WL 2349591 at \*2 (D.N.J. May 4, 2016) ("Torrent II"), it reaches a different result here, given Apotex's significantly more robust allegations. In Torrent II, Torrent conceded that its antitrust injury claim rested "exclusively upon its individual incurrence of defense costs in this litigation." Id. As a result, this Court dismissed Torrent's sham litigation counterclaim because Torrent only alleged that Otsuka's claimed conduct "had an adverse financial effect" on Torrent alone, and not on the entire market. Id. Here, as explained supra, Apotex has pled allegations of an overall market impact instead of mere impact on itself alone. Thus, Apotex has alleged sufficient facts to demonstrate the first prong of antitrust injury.

15. Otsuka argues, however, that Apotex has failed to establish that it has suffered an antitrust injury because none of Apotex's alleged injuries resulted from Otsuka's unlawful or anticompetitive acts. (Otsuka Br. at 5.) In other words, none of Otsuka's anticompetitive activities proximately caused the delayed launch of Apotex's generic aripiprazole products. (Reply Br. at 2.) Otsuka claims, for example, that none of Otsuka's legal actions against the generics "caused or bore any nexus to the delay of the FDA's approval of Apotex's ANDA." Id. Here,



Apotex has pled a number of possible facts that, accepted as true, would support a nexus between Otsuka's filing of this lawsuit and Apotex's delay in approval of its ANDA from April to July 2015. These include (1) Otsuka's present action against Apotex for infringement; (2) Otsuka's March 2015 motion for a TRO and preliminary injunction, (3) Otsuka's April 2015 suit against the FDA in federal district court in Maryland, and (4) Apotex's eventual reception of approval for the ANDA July 24, 2015. (Countercl. at ¶¶ 92-93, 95, 97.) If Court accepted Otsuka's position, "antitrust standing under the Hatch-Waxman Act would be wholly contingent on the vagaries of the timing of agency action." Apotex I, 143 F. Supp. 3d at 194 (citing Bristol-Myers Squibb Co. v. Ben Venue Labs., 90 F. Supp. 2d 540, 545 (D.N.J. 2000)).

16. In its reply brief, Otsuka requests, for the first time, that the Court take judicial notice of the fact that Otsuka was not the cause of delay in FDA approval. (Reply Br. at 4, Exhibit 7 to Otsuka's Br.) Judicial notice is governed by Federal Rule of Evidence 201, which permits the Court to notice an adjudicative fact "that is not subject to reasonable dispute because it (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot be reasonably be questioned. FED. R. EVID. 201(a)-(b). The information that Otsuka



urges this Court to notice is not of the kind contemplated by the judicial notice doctrine because such evidence is itself a matter of continuing litigation and not yet established. Otsuka relies on the contents of a private FDA letter to Apotex in which it makes certain statements regarding this litigation, which has been filed under seal and need not be disclosed herein. (Exhibit 7 to Otsuka's Br. at 2.) Courts "may take judicial notice of public records of the FDA." Torrent I, 118 F. Supp. 3d at 655 n. 7 (emphasis added); see Apotex Inc. v. Acorda Therapeutics, Inc., 823 F.3d 51, 60 (2d Cir. 2016) (taking judicial notice of "publicly available" FDA "Guidance for Industry"); Torrent I, 118 F. Supp. 3d at 655 (taking judicial notice of an FDA press release available on the agency's website); In re Wellbutrin SR/Zyban Antitrust Litigation, 281 F. Supp. 2d 751, 754 n. 2 (E.D. Pa 2003) (taking judicial notice of a "published report" that was "posted on the official FDA website"). However, this particular letter was not publicly available, and the language is not necessarily conclusive of causation of market entry delay at this point in the proceedings. Torrent I, 118 F. Supp. 3d at 655 n. 7. As a result, the Court will decline to take judicial notice of a statement by the FDA in a non-public document.

17. For these reasons, the Court finds that Apotex's allegations, accepted as true, sufficiently state an antitrust



injury, and rejects Otsuka's position that Apotex's antitrust Counterclaim should be dismissed for lack of antitrust standing.<sup>1</sup>

18. The Court next addresses whether Apotex states a plausible Counterclaim for patent misuse.

19. The "key inquiry under the patent misuse doctrine is whether ... the patentee has "'impermissibly broaden[ed] the physical or temporal scope' of the patent grant with an anticompetitive effect."<sup>2</sup> Princo Corp. v. Int'l Trade Comm'n, 616 F.3d 1318, 1328 (Fed. Cir. 2010) (quoting Windsurfing Int'l, Inc. v. AMF, Inc., 782 F.2d 995, 1001 (Fed. Cir. 1986)). A plausible claim for patent misuse must, in turn, include an allegation that the patentee has impermissibly attempted to enlarge the scope of its patent monopoly. See, e.g., Torrent I, 118 F. Supp. 3d at 659; Micron Tech., Inc. v. Rambus Inc., 917 F. Supp. 2d 300, 320 n.19 (D. Del. 2013); Altana Pharma AG v. Teva Pharm. USA, Inc., No. 04-2355, 2012 WL 2068611 (D.N.J. June

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<sup>1</sup> Moreover, the existence of antitrust injury "involves complex questions of fact," ill-suited for resolution upon a motion to dismiss. Schuylkill Energy Res., Inc. v. Pa. Power & Light Co., 113 F.3d 405, 417 (3d Cir. 1997) (citing Brader v. Allegheny Gen. Hosp., 64 F.3d 869, 876 (3d Cir. 1995) (collecting cases)); see also In re Niaspan Antitrust Litig., 42 F. Supp. 3d at 757 n.19 (collecting cases that have declined to resolve the existence of antitrust injury through motions to dismiss). As a result, even if Apotex's allegations proved sparse, which they do not, resolving the issue of antitrust injury exceeds the scope of this limited Rule 12(b)(6) motion.

<sup>2</sup> In Torrent I, the Court provided a detailed discussion of the origination of this doctrine. See Torrent I, 118 F. Supp. 3d at 658-59.



7, 2012); Cordance Corp. v. Amazon.com, Inc., 727 F. Supp. 2d 310, 333-34 (D. Del. July 23, 2010); In re Gabapentin Patent Litig., 648 F. Supp. 2d 641, 652 (D.N.J. 2009). As a result, in Torrent I, the Court dismissed the patent misuse counterclaim without prejudice, because the counterclaim lacked the "essential allegation" of an "improper expansion of the physical or temporal breadth of the disputed patents." Torrent I, 118 F. Supp. 3d at 659.

20. While this Court recently addressed similar allegations in Torrent I, it reaches a different result here, given Apotex's more specific factual allegations. In Torrent I, this Court dismissed Torrent's patent misuse Counterclaim it "contain[ed] no allegation concerning any improper expansion of the physical or temporal breadth of the disputed patent." Id. On the other hand, Apotex's patent misuse Counterclaim plainly alleges that this action amounts to an impermissible attempt to prolong the life of Otsuka's long-standing monopoly in the aripiprazole market. (See generally Countercl. at ¶¶ 124-131.) Indeed, Apotex specifically alleges that Otsuka has wielded the Patents-in-Suit beyond their permissible "physical or temporal scope" in order to obtain a market advantage.<sup>3</sup> (Id. at ¶ 129.)

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<sup>3</sup> For that reason, Apotex's Counterclaim differs markedly from the patent misuse Counterclaim this Court found insufficient in Torrent I. See Torrent I, 118 F. Supp. 3d at 659.



These allegations, accepted as true for purposes of this Rule 12(b)(6) motion, sufficiently state a claim of patent misuse. Bayer AG v. Housey Pharmaceuticals, Inc., 169 F. Supp. 2d 328, 331 (D. Del. 2001) (finding similar allegations sufficient), aff'd, 340 F.3d 1367 (Fed. Cir. 2003).

21. The Court lastly addresses Otsuka's request to bifurcate and stay. Under Federal Rule of Civil Procedure 42(b), the Court may "order a separate trial of one or more separate issues, claims, crossclaims, counterclaims, or third-party claims," in order to encourage "convenience, to avoid prejudice, or to expedite and economize." FED. R. CIV. P. 42(b). In determining whether to bifurcate, courts carefully balance "considerations of convenience, avoidance of prejudice, and efficiency," and must ensure the preservation of the litigant's constitutional right to a jury. Apotex I, 143 F. Supp. 3d at 197.

22. Considering the various factors presented in this action,<sup>4</sup> the Court will bifurcate and stay Apotex's antitrust and patent misuse Counterclaims. Critically, like Apotex I, resolution of the patent infringement issues may moot these

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<sup>4</sup> As this Court noted in Apotex I, for reasons of efficiency and avoiding needless expense, the Court will again stay Apotex's Counterclaims for all purposes (discovery or otherwise), pending resolution of Otsuka's patent infringement claims. 143 F. Supp. 3d at 197.



Counterclaims, thereby preserving judicial economy. Id.

Bifurcation of these Counterclaims from the already-complex patent infringement claims further enhances "the parties' right to jury trial by making the issues the jury must consider less complex." Warner Lambert Co. v. Purepac Pharm. Co., Nos. 98-2749, 99-5948, 00-2053, 2000 WL 34213890, \*11 (D.N.J. Dec. 22, 2000) (internal quotation marks omitted).

23. The Court will therefore follow the practice of separating for trial patent issues and antitrust issues. See Apotex I, 143 F. Supp. 3d at 197 (bifurcating and staying substantively identical antitrust counterclaims).

24. For the reasons stated above, Otsuka's motion will be denied to the extent it seeks dismissal of Apotex's antitrust and patent misuse Counterclaims. Torrent's antitrust and patent misuse Counterclaims will, however, be bifurcated and stayed, pending resolution of the patent infringement issues.

25. An accompanying Order will be entered.

August 25, 2016  
Date

s/ Jerome B. Simandle  
JEROME B. SIMANDLE  
Chief U.S. District Judge